K111096
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510(k) Summary

JUN 24 2011

Vasomedical-Biox Combined 12 Channel Ambulatory ECG and Blood Pressure Recorder Model 2302 and Ambulatory Blood Pressure Monitor (ABPM) Model 1804

1. **Date Prepared:** April 18, 2011

2. **Submitter's Name: and Address** Vasomedical, Inc.
180 Linden Ave.
Westbury, NY 11590

3. **Contact Person:** Richard Gordon
Manager, Regulatory and Quality Affairs
Vasomedical, Inc.
Telephone: (516) 997-4600
Facsimile: (516) 997-2299
E-mail: rgordon@vasomedical.com

4. **Device Names:**
a) Combined 12 Channel Ambulatory ECG and Blood Pressure Recorder, Model 2302
b) Ambulatory Blood Pressure Monitor (ABPM), Model 1804

Proprietary Names:
a) Vasomedical-Biox Combined 12 Channel Ambulatory ECG and Blood Pressure Recorder Model 2302
b) Vasomedical-Biox Ambulatory Blood Pressure Recorder (ABPM) Model 1804

Common Name:
a) Combined 12 Channel Ambulatory ECG and Blood Pressure Recorder Model 2302
b) Ambulatory Blood Pressure Monitor (ABPM) System Model 1804

Classification Name: 870.2800 Medical Magnetic Tape Recorder
870.1130 Noninvasive Blood Pressure Measurement System

5. **Predicate Device:** Vasomedical - Biox, 3 Channel Ambulatory ECG and Blood Pressure Recorder 2301 was granted **FDA 510(k) clearance on April 2, 2010 (k092785).**

6. **Device Description:** Vasomedical-Biox Combined 12 Channel Ambulatory ECG and Blood Pressure Recorder Model 2302 is intended to be used as a combined Holter Ambulatory Electrocardiograph device and a non-invasive Ambulatory Blood Pressure Monitor for the purpose of screening ECG rhythms and blood pressure measurements for periods to 24 hours.

Blood Pressure measurements are obtained using oscillometric signals at intervals set by the physician or on demand. Cardiac rhythm is acquired by 12 Channel ECG signals. The Recorders are intended for adults and children over the age of six years old.

The Model 2302 Recorder is a modified version of Model 2301 which **FDA granted clearance on April 2, 2010 (k092785),** with 3-Channel ECG replaced by 12-Channel ECG.

Vasomedical-Biox Ambulatory Blood Pressure Recorder Model 1804 is intended to be used as a non-invasive ABP Monitor for the purpose of recording blood pressure measurements also for a period of 24 hours. The Recorders are intended for adults and children over the age of six years old.

The Model 1804 Ambulatory Blood Pressure Recorder is a modified version of Model 2301. Model 2301 records both ECG and BP signals and Model 1804 is a Blood Pressure ***only*** Recorder.

The Recorders are portable, microprocessor based devices that are worn by a patient with the use of a supplied Carrying Case and Strap.

Models 2302 and 1804 specifications are listed in **Table 1** below:

	Model 2302	**Model 1804**
Lead	12	NA
Electrode	10	NA
Lead wire type	10	NA
Display	LCD	LCD
Batteries	4 x AA Alkaline	4 x AA Alkaline
BP Cuff	Medium (standard) (Small and Large are optional)	Medium (standard) (Small and Large are optional)
Carrying Case/ Strap	Supplied	Supplied
Card Reader	Supplied	Supplied

	Model 2302	Model 1804
Dimensions	4.88 x 2.68 x 1.22"	4.88 x 2.68 x 1.22"
Weight	6.35 oz.	6.34 oz.
Storage	SD Memory Card	SD Memory Card
Memory Capacity	1 GB or more	1 GB or more
Sample Rate	Max. 10000 Hz 256 Hz/Channel 2048 Hz Pacemaker Detection	Max. 10000 Hz 256 Hz/Channel 2048 Hz Pacemaker Detection
Resolution	12 Bits	12 Bits
Infrared Adaptor	Supplied	Supplied

Table 1: Model 2302 and 1804 Specifications

7. **Intended Use:**

Vasomedical-Biox Combined 12 Channel Ambulatory ECG and Blood Pressure Recorder, Model 2302, is a Non-Invasive device intended to acquire Ambulatory 12 Channel ECG signals and non- invasive oscillometric Blood Pressure signals from the upper body surfaces. Cardiac rhythm is acquired via ECG signals.

Vasomedical-Biox Model 1804 Ambulatory BP Recorder is a non-invasive device intended to acquire ambulatory non-invasive oscillometric Blood Pressure signals from the upper body surfaces. This ABP Recorder functions exactly the same as Model 2301/2302 for measurement and recording of Blood Pressure signals.

The Recorders are intended for adults and children who are over the age of six years.

The system is only for measurement, recording and display. It makes no diagnosis.

Refer to Attachments I and II, Vasomedical-Biox Model 2301/2302 AECGBP and Model 1804 ABPM Instruction Manual for Users, Sections 2.2, Indications for Use, 2.2.1 Intended Use and 2.2.2 for

Contraindications.

8. Comparison of Technological Characteristics: Technological and functional characteristics of the devices listed in this Special 510(k) Notification for Modification are essentially the same as those of the predicate device. The device listed in this 510(k) Premarket Notification is therefore substantially equivalent to the predicate device.

"The Intended Use of the modified devices as described in its labeling, has not changed as a result of the modifications".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Vasomedical, Inc.
c/o Mr. Richard E. Gordon
Manager, Regulatory and Quality Affairs
180 Linden Avenue
Westbury, NY 11590

JUN 24 2011

Re: K111096
Trade/Device Name: Vasomedical-Biox Combined 12-Channel Ambulatory ECG and Blood Pressure Recorder (Model 2302) with CB Series ECG and ABP Analysis Software and Vasomedical-Biox Ambulatory Blood Pressure Monitor (ABPM) (Model 1804)
Regulatory Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: II (two)
Product Code: DSH, DXN
Dated: May 25, 2011
Received: May 26, 2011

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: k

Device Names:

a) Vasomedical-Biox Combined 12 Channel Ambulatory ECG And Blood Pressure Recorder, Model 2302 with CB Series ECG and ABP Analysis Software

b) Vasomedical-Biox Ambulatory Blood Pressure Monitor (ABPM), Model 1804

Indications for Use:

Vasomedical-Biox Model 2302 Combined 12 Channel Ambulatory ECG and Blood Pressure Recorder is a Non-Invasive device intended to acquire Ambulatory 12 Channel ECG signals and non- invasive oscillometric Blood Pressure signals from the upper body surfaces. Cardiac rhythm is acquired via ECG signals.

Vasomedical-Biox Model 1804 Ambulatory BP Recorder is a non-invasive device intended to acquire ambulatory non-invasive oscillometric Blood Pressure signals from the upper body surfaces.

The Recorders are intended for adults and children who are over the age of six years.

The Models 2302 and 1804 work with the CB Series ECG and ABP Analysis Software which has been previously cleared under (k)092785

"The Intended Use of the modified devices as described in its labeling, has not changed as a result of the modifications".

The system is only for measurement, recording and display. It makes no diagnosis.

Prescription Use: YES (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use: NO** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111096